



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0658]

Vithal K. Patel; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Vithal K. Patel (Mr. Patel) and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Mr. Patel for 1 year from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Patel was convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of drug products under the FD&C Act and that the type of conduct underlying the conviction undermined the process for the regulation of drugs. In determining the appropriateness and period of Mr. Patel's debarment, FDA considered the relevant factors listed in the FD&C Act. Mr. Patel has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application for termination of debarment by Mr. Patel under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your

application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2011-N-0658.

Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency

will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds: (1) that the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of any drug product

under the FD&C Act and (2) that the type of conduct serving as the basis of the conviction undermines the process for the regulation of drugs.

On August 7, 2007, Mr. Patel pled guilty to a felony count of conspiracy to distribute misbranded and adulterated drugs in violation of 18 U.S.C. 371. On December 16, 2010, the U.S. District Court for the District of New Jersey entered the conviction, sentenced Mr. Patel to 2 years of probation, and imposed a \$3,000 fine. Mr. Patel's conviction stemmed from his employment at Able Laboratories, Inc. (Able), where he was a Research and Development Manager and later the Associate Director for Technical Service. Mr. Patel and others conspired to cause the introduction of misbranded and adulterated drugs into interstate commerce with the intent to defraud and mislead the United States, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)). According to the criminal information to which he pled guilty under a plea agreement, Mr. Patel and his coconspirators agreed to violate FDA's regulations regarding good manufacturing practice for drugs by, among other things, manipulating and falsifying testing data and information. Mr. Patel specifically admitted to an overt act in furtherance of the conspiracy, namely supervising the manipulation of the process for manufacturing promethazine, a prescription antihistamine medication.

By letter dated January 6, 2012, FDA's Office of Regulatory Affairs (ORA) notified Mr. Patel of an opportunity for a hearing on a proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application. In its proposal, ORA concluded that Mr. Patel should be debarred for 5 years based on four applicable considerations in section 306(c)(3) of the FD&C Act: (1) the nature and seriousness of his offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps taken to mitigate the impact on the public, and (4) prior convictions involving matters within FDA's jurisdiction. ORA found that the first three of those considerations weigh in favor of debarment and noted, as to the fourth consideration, that FDA is unaware of any prior convictions.

In a letter dated March 8, 2012, Mr. Patel requested a hearing on the proposal and submitted materials and arguments in support of his request. In his submission, Mr. Patel acknowledges his conviction of a conspiracy to commit a felony under Federal law and does not dispute that the conduct underlying that conviction related to the regulation of a drug product or that conduct of that type undermines the process for the regulation of drugs. He argues, however, that with respect to the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act, there are genuine and substantial issues of fact for resolution at a hearing.

II. Statutory and Regulatory Framework Regarding Part 12 Hearings

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Mr. Patel's submission. Under § 12.24(a)(2) (21 CFR 12.24(a)(2)), the Agency reviews a hearing request to determine whether a hearing is justified. FDA has the authority to deny a hearing when it appears from the hearing request that there are no material disputes of fact. See *Costle v. Pacific Legal Found.*, 445 U.S. 198, 214 (1980) (a party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing"), *reh'g denied*, 446 U.S. 947 (1980), citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-21 (1973); *Pineapple Growers Ass'n v. FDA*, 673 F.2d 1083, 1085-86 (9th Cir. 1982) (holding that no hearing is necessary unless "material issues of fact" have been raised).

In determining whether there are material issues of fact suitable for a hearing, FDA considers the specific criteria set out in § 12.24(b) and grants a hearing only if the material submitted in support of the request shows the following: (1) there is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing,

would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the Agency concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the Agency concludes that the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, and 12.22, and in the notice of an opportunity for hearing are met.

III. Arguments

In his request for a hearing, Mr. Patel challenges ORA's findings with respect to the three considerations that it concluded weighed in favor of his debarment. Mr. Patel also contends that there are two additional considerations under section 306(c)(3) of the FD&C Act that were not considered by ORA and should weigh in his favor against debarment. Section 306(c)(3) of the FD&C Act explicitly requires that FDA consider, "where applicable," certain factors "[i]n determining the appropriateness and the period of debarment" for any permissive debarment.

A. Nature and Seriousness of the Offense

Regarding the nature and seriousness of his offense, Mr. Patel contends that, in reaching its conclusion regarding the nature and seriousness of his felony offense, ORA failed to consider certain important facts. Specifically, Mr. Patel argues that the overt act underlying his conspiracy conviction--namely supervising manipulation of the process for manufacturing promethazine--involved merely failing to document or follow proper procedures for a nitrogen flush and "posed no danger to the end users, the public at large, or coworkers at Able." He reasons that, "as an inert gas, nitrogen could not possibly interact with the [promethazine hydrochloride] in any way." Mr. Patel maintains that this factor should therefore not have

weighed in favor of his debarment. However, as part of his guilty plea, Mr. Patel admitted to conspiring to cause the introduction of misbranded and adulterated products into interstate commerce, with the intent to defraud and mislead the United States. Therefore, even assuming that Mr. Patel did not intend for his conduct to harm anyone, the offense to which Mr. Patel pled guilty remains serious and weighs in favor of debarment.

B. Nature and Extent of Management Participation in the Offense

As to the consideration addressing the nature and extent of management participation, Mr. Patel argues that ORA's analysis overlooks the nature and extent of Mr. Patel's management participation in the offense and reaches the conclusion that this factor is unfavorable "simply because Mr. Patel was not an entry level worker." In fact, Mr. Patel insists that he "never participated in the production of commercial products at Able Labs" and, as such, "exercised no 'management' authority in connection with the nitrogen flush" and "had no input into or control over Able Labs' 'corporate policies and practices' or 'institutional controls' with respect to production processes." To the contrary, Mr. Patel emphasizes that "both the United States Attorney's Office and [the court] confirmed that Mr. Patel was acting on the order of his superior managers to observe the nitrogen flush and was in fear the he would be terminated if he refused."

In the proposal to debar, ORA stated:

As a Research and Development Manager and Associate Director of Technical Service, you were responsible for supervising numerous chemists and technicians who manufactured test batches to ensure product safety and effectiveness. Your management position also entailed monitoring the chemists' compliance with GMPs, as required by FDA, and SOPs established by the company and ensuring compliance with Able's SOPs, including protocols for investigating, logging, and archiving any aberrant, deviant, or failing analytical laboratory results. As supervisor, you held a position of authority in which your conduct served as an example to other employees. Accordingly, the Agency will consider this an unfavorable factor.

Mr. Patel does not dispute that he was in a supervisory position at Able. Even assuming Mr. Patel reasonably feared termination related to the conspiracy he joined, Mr. Patel does not contest that he worked in a position of authority at Able and had the responsibilities outlined in ORA's proposal to debar him for 5 years. Therefore, Mr. Patel has failed to create an issue for

hearing with respect to whether the nature and extent of his management participation in the offense should weigh against debarment.

C. Changes in Ownership, Management, or Operations

Next, Mr. Patel argues that ORA incorrectly failed to consider “whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,” under section 306(c)(3)(D) of the FD&C Act. Mr. Patel states that an offense will not occur here in the future because “Able Labs is now defunct” and he “voluntarily left the pharmaceutical industry in 2007.”

FDA must consider, where applicable, “whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.” The considerations in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. This consideration does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming for the sake of argument that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, Mr. Patel’s contention that, because he voluntarily left the pharmaceutical industry he has provided reasonable assurances that he will not commit the offense again given the opportunity, fails to create a genuine and substantial issue of fact that warrants a hearing. Furthermore, given that this debarment proceeding focuses on Mr. Patel rather than Able, it is immaterial that Able Labs is no longer in business.

D. Abbreviated New Drug Applications (ANDAs)

Mr. Patel argues that “whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all

pending abbreviated drug applications are free of fraud or material false statements” under section 306(c)(3)(E) of the FD&C Act should be considered in his favor because the improper manufacturing procedures for which Mr. Patel was convicted “had no relation to a drug application in any way.” This factor is only relevant for persons that have an ANDA. Mr. Patel has not presented any evidence that he has any existing abbreviated drug applications for consideration in his own name, and thus, this factor is not relevant in determining the appropriateness and length of debarment and fails to create a genuine and substantial issue of fact that warrants a hearing.

E. Nature and Extent of Voluntary Steps to Mitigate

Lastly, under section 306(c)(3)(C) of the FD&C Act, in determining the appropriateness and period of debarment, FDA must consider, where applicable, “the nature and extent of voluntary steps to mitigate the effect on the public,” including whether the person took specified corrective actions after the criminal violation or fully cooperated with any investigations. In the proposal to debar, ORA concluded that Mr. Patel’s “failure to take voluntary steps to mitigate the offense [he] committed” rendered this an unfavorable factor. ORA based this conclusion on the fact that “FDA has no information demonstrating that [Mr. Patel] took any voluntary steps to mitigate the impact of [his] actions on the public.”

In his hearing request, Mr. Patel maintains that he did, in fact, take voluntary steps to mitigate the effect of his offense on the public, including “full cooperation with any investigations” under section 306(c)(3)(C) of the FD&C Act. In support, Mr. Patel submits a letter from an Assistant U.S. Attorney who participated in his prosecution and a transcript of his sentencing. Quoting this letter, Mr. Patel maintains that his cooperation enabled the Government to “expand its investigation to other individuals and to develop a better understanding of the misbranding conspiracy at Able Labs” and “permitted the government to vet the information...received from other individuals and to follow new leads.” Furthermore, he adds that he provided valuable “details about events and discussions demonstrating that Able Labs’

management had made changes to drug protocols.” He relies on these submissions to demonstrate not only that he cooperated with the government and contributed to the successful prosecution of others, including Able’s top manager, but also that the government argued at his sentencing that he provided “substantial assistance” in those investigations and moved for a more lenient sentence on that basis. Mr. Patel’s account of his cooperation and substantial assistance in the investigation is undisputed and supported by the transcript of his sentencing. Therefore, the nature and extent of the voluntary steps Mr. Patel took to mitigate the impact of his offense on the public under section 306(c)(3)(C) of the FD&C Act weigh in Mr. Patel’s favor in determining the appropriateness and period of debarment.

Given the undisputed facts described above, and after considering the applicable factors listed in section 306(c)(3) of the FD&C Act, the Chief Scientist finds that Mr. Patel’s conviction warrants a 1-year debarment period. It is undisputed that Mr. Patel pled guilty to a serious offense and that he participated in the offense as a supervisor. However, Mr. Patel took significant steps to mitigate the effect of his offense on the public, as described in the Assistant U.S. Attorney’s letter, and he has no prior convictions. Particularly in light of FDA’s strong public policy interest in encouraging cooperation with authorities engaged in investigating wrongdoing related to the Agency’s regulation of drugs, as reflected in section 306(c)(3)(C) of the FD&C Act, the Chief Scientist has determined that a debarment period of only 1 year is appropriate in this case.

IV. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(II) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs, finds that: (1) Mr. Patel has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and (2) that the conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA

has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 1 year is appropriate.

As a result of the foregoing findings, Mr. Patel is debarred for 1 year from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Mr. Patel, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Patel, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Patel during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: July 27, 2021.

Denise Hinton,

Chief Scientist.

[FR Doc. 2021-16350 Filed: 7/30/2021 8:45 am; Publication Date: 8/2/2021]